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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PRODUCTS, L.P., and JANSSEN SCIENCES IRELAND UC, Plaintiffs, v. DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., LAURUS LABS, LTD., and PHARMAQ, INC., Defendants.	)	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Products, L.P. and Janssen Sciences Ireland UC (together, "Janssen" or "Plaintiffs") for their Complaint against Defendants Dr. Reddy's Laboratories, Inc. ("DRL USA"), Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") (together, "DRL"), Laurus Labs, Ltd. ("Laurus"), and PharmaQ, Inc. ("PharmaQ") (collectively, "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement by Defendants of U.S. Patent No. 8,518,987 (the "'987 Patent") arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq., and for a declaratory judgment of infringement of U.S. Patent Nos. 7,126,015 (the "'015 Patent") and 7,595,408 (the "'408 Patent") under 35 U.S.C. §§ 1 et seq., 28 U.S.C. §§ 2201 and 2202.

2. This action arises out of Defendants' filing of Abbreviated New Drug Application No. 21-1578 (the "ANDA"), supported by Drug Master File No. 031198 (the "DMF"), seeking approval to sell generic versions of Janssen's highly successful PREZISTA® (darunavir) 600 mg and 800 mg tablets (the "ANDA Products") prior to the expiration of the '987 Patent, the '015 Patent, and the '408 Patent (together, the "patents-in-suit").

THE PARTIES

3. Plaintiff Janssen Products, L.P., is a partnership organized under the laws of the State of New Jersey, having its headquarters and principal place of business at 800/850 Ridgeview Drive, Horsham, PA 19044.

4. Plaintiff Janssen Sciences Ireland UC is an Irish corporation having its principal place of business at Eastgate Village, Eastgate, Little Island, County Cork, Ireland.

5. On information and belief, DRL USA is a New Jersey corporation with a principal place of business in Princeton, New Jersey. On information and belief, DRL USA is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. On information and belief, DRL USA is a wholly owned subsidiary, alter ago, and agent of DRL Ltd. On information and belief, DRL USA is the agent of DRL Ltd. and Laurus with respect to the ANDA.

6. On information and belief, DRL Ltd. is a company organized and existing under the laws of India, with a registered office at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India. On information and belief, DRL Ltd. is in the business of, among other things, marketing and selling generic copies of branded pharmaceutical products for the U.S. market, alone and/or through its wholly owned subsidiary, alter ego, and agent, DRL USA. On information and belief, DRL Ltd. is the holder of the ANDA.

7. On information and belief, Laurus is a company organized and existing under the laws of India, with a registered office at Plot No. 21, Jawaharlal Nehru Pharma City, Parawada, Visakhapatnam, Andhra Pradesh, 531021, India. On information and belief, Laurus is in the business of, among other things, manufacturing generic copies of branded pharmaceutical products and active pharmaceutical ingredients ("API") for generic copies of branded pharmaceutical products for the U.S. market, alone and/or in partnership with other generic drug companies, including DRL. On information and belief, Laurus is the holder of the DMF. On information and belief, Laurus and DRL have collaborated on the submission of the ANDA and will share the profits and costs from the manufacturing and sales of the ANDA Products. On information and belief, Laurus will manufacture the ANDA Products and the API for the ANDA Products.

8. On information and belief, PharmaQ is a New Jersey corporation with a principal place of business in Parsipanny, New Jersey. On information and belief, PharmaQ is in the business of, among other things, assisting generic drug companies with the process of manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. On information and belief, PharmaQ is the U.S. regulatory agent for Laurus with respect to the DMF.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. On information and belief, this Court has personal jurisdiction over DRL USA, *inter alia*, because DRL USA's principal place of business is located in New Jersey and because DRL USA is a corporation organized and existing under the laws of New Jersey.

11. On information and belief, this Court has personal jurisdiction over DRL USA because DRL USA has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, DRL USA has had persistent and continuous contacts with this judicial district, including developing, manufacturing, marketing, and selling pharmaceutical products that are sold in this judicial district.

12. On information and belief, DRL USA derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

13. On information and belief, DRL USA has invoked this Court's jurisdiction as Plaintiff in civil actions concerning allegations of patent infringement. *See, e.g., Dr. Reddy's Laboratories, Inc. et al. v. AstraZeneca AB et al.*, Case No. 3:15-cv-08128-MLC-TJB (D.N.J. Nov. 17, 2015); *Dr. Reddy's Laboratories, Inc. et al. v. Purdue Pharmaceutical Products, L.P. et al.*, Case No. 2:14-cv-03230-JLL-JAD (D.N.J. May 20, 2014). On information and belief, DRL USA has also invoked this Court's jurisdiction as Counterclaimant in Hatch-Waxman litigations. *See, e.g.*, Answer and Counterclaims (Dkt. 79), *Sumimoto Dainippon Pharma Co., Ltd. et al. v. Aurobindo Pharma Ltd., et al.*, Case No. 2:18-cv-02620-SRC-CLW (D.N.J. Apr. 11, 2018);

Answer and Counterclaims (Dkt. 34), *Teva Pharmaceuticals USA, Inc. et al. v Dr. Reddy's Laboratories Ltd. et al.*, Case No. 3:17-cv-00517-FLW-DEA (D.N.J. Apr. 18, 2017). On information and belief, DRL USA has also previously consented to personal jurisdiction in this district in Hatch-Waxman actions. *See, e.g.*, Answer (Dkt. 79) at ¶ 60, *Sumimoto Dainippon Pharma Co., Ltd. et al. v. Aurobindo Pharma Ltd., et al.*, Case No. 2:18-cv-02620-SRC-CLW (D.N.J. Apr. 11, 2018) ("DRL does not contest personal jurisdiction for purposes of this case only"); Answer (Dkt. No. 11) at ¶ 19, *Horizon Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc.*, Case No. 3:16-cv-9035-MLC-DEA (D.N.J. Jan. 4, 2017) ("DRL admits jurisdiction and venue in this case").

14. On information and belief, DRL USA acts as the agent and alter ego of DRL Ltd. On information and belief, DRL USA has submitted regulatory filings for generic pharmaceutical products to the FDA on behalf of DRL Ltd., including the ANDA seeking FDA approval to market DRL's ANDA Products before expiration of the patents-in-suit.

15. On information and belief, DRL USA and DRL Ltd. operate and act in concert as an integrated, unitary business.

16. On information and belief, DRL USA acts as the agent of Laurus with respect to the ANDA. On information and belief, DRL USA submitted regulatory filings for generic pharmaceutical products to the FDA on behalf of Laurus, including the ANDA seeking FDA approval to market DRL's ANDA Products before expiration of the patents-in-suit.

17. On information and belief, this Court has personal jurisdiction over DRL Ltd. because DRL Ltd. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, acting itself and/or through its wholly owned subsidiary, alter ego, and

agent, DRL USA, DRL Ltd. has had persistent and continuous contacts with this judicial district, including developing, manufacturing, marketing, and selling pharmaceutical products that are sold in this judicial district.

18. On information and belief, DRL Ltd. has a regular and established place of business located at the principal place of business of DRL USA in Princeton, New Jersey, where DRL Ltd. regularly conducts business itself and/or through its wholly owned subsidiary, alter ego, and agent, DRL USA.

19. On information and belief, DRL Ltd., directly and/or through its subsidiary, alter ego, and agent, DRL USA, markets, distributes and sells generic pharmaceutical products throughout the United States, including in this judicial district.

20. On information and belief, DRL Ltd. derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district, directly and/or through its subsidiary, alter ego, and agent, DRL USA.

21. On information and belief, DRL Ltd., directly and/or through its subsidiary, alter ego, and agent, DRL USA, has an extensive network of physicians, hospitals, long-term care facilities, group purchasing organizations, retailers, wholesalers and distributors in this judicial district.

22. On information and belief, DRL Ltd. has invoked this Court's jurisdiction as Plaintiff in civil actions concerning allegations of patent infringement. *See, e.g.*, *Dr. Reddy's Laboratories, Inc. et al. v. AstraZeneca AB et al.*, Case No. 3:15-cv-08128-MLC-TJB (D.N.J. Nov. 17, 2015); *Dr. Reddy's Laboratories, Inc. et al. v. Purdue Pharmaceutical Products, L.P. et al.*, Case No. 2:14-cv-03230-JLL-JAD (D.N.J. May 20, 2014); *Dr. Reddy's Laboratories, Ltd. et al. v. Eli Lilly and Company*, Case No. 3:09-cv-00192-GEB-JJH (D.N.J. Jan. 8, 2009); *Dr.*

Reddy's Laboratories, Ltd. et al. v. AstraZeneca AB et al., Case No. 3:08-cv-02496-JAP-TJB (D.N.J. May 19, 2008). On information and belief, DRL Ltd. has also invoked this Court's jurisdiction as Counterclaimant in Hatch-Waxman litigation. *See, e.g.*, Answer and Counterclaims (Dkt. 79), *Sumimoto Dainippon Pharma Co., Ltd. et al. v. Aurobindo Pharma Ltd., et al.*, Case No. 2:18-cv-02620-SRC-CLW (D.N.J. Apr. 11, 2018); Answer and Counterclaims (Dkt. 34), *Teva Pharmaceuticals USA, Inc. et al. v Dr. Reddy's Laboratories Ltd. et al.*, Case No. 3:17-cv-00517-FLW-DEA (D.N.J. Apr. 18, 2017).

23. On information and belief, DRL Ltd. has also previously consented to personal jurisdiction in this district in Hatch-Waxman actions. *See, e.g.*, Answer (Dkt. 79) at ¶ 46, *Sumimoto Dainippon Pharma Co., Ltd. et al. v. Aurobindo Pharma Ltd., et al.*, Case No. 2:18-cv-02620-SRC-CLW (D.N.J. Apr. 11, 2018) ("DRL does not contest personal jurisdiction for purposes of this case only"); Answer (Dkt. No. 11) at ¶ 19, *Horizon Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc.*, Case No. 3:16-cv-9035-MLC-DEA (D.N.J. Jan. 4, 2017) ("DRL admits jurisdiction and venue in this case").

24. On information and belief, DRL Ltd. has been and is engaging in activities directed toward infringement of the patents-in-suit by, among other things, preparing and submitting the ANDA seeking FDA approval to market the ANDA Products before expiration of the patents-in-suit throughout the United States, including in New Jersey.

25. On information and belief and as stated in DRL's Paragraph IV Letter dated April 13, 2018 concerning the ANDA Products (the "Paragraph IV Letter"), DRL intends to engage in the commercial manufacture, use, or sale of the ANDA Products before expiration of the patents-in-suit throughout the United States, including in New Jersey. The conduct of DRL Ltd., acting itself and/or through its subsidiary, agent and alter ego, DRL USA, will

therefore cause injury to Janssen in New Jersey.

26. On information and belief, this Court has personal jurisdiction over Laurus because Laurus has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Laurus, acting itself and/or through its agents, including DRL, has had persistent and continuous contacts with this judicial district, including developing, manufacturing, marketing, and selling pharmaceutical products that are sold in this judicial district.

27. According to an investor presentation from November 2017, Laurus has "[e]ntered into a partnership" with DRL "for development & sale of ARV [anti-retroviral] FDFs [final dosage forms] for US market on profit and cost sharing basis."[1] On information and belief, Laurus will share the profits and costs of the sale and manufacture of the ANDA Products with DRL.

28. On information and belief, with respect to ANDA No. 21-1578 and other applications to sell generic drugs, Laurus has a regular and established place of business located at the principal place of business of DRL USA, where Laurus regularly conducts business itself and/or through its agents, DRL Ltd. and DRL USA.

29. On information and belief, Laurus also has appointed PharmaQ, Inc. ("PharmaQ"), a New Jersey corporation with its principal place of business in Parsippany N.J., as its U.S. Regulatory Agent with respect to the DMF. Pursuant to this delegation, PharmaQ is permitted to communicate with FDA on behalf of Laurus and to provide authorization for other parties to rely on the DMF.

[1] http://www.lauruslabs.com/sitesall/themes/lauruslab//Investors/PDF/Q2/Q2_H1_FY_2017-18_Investor_Presentation.pdf.

30. On information and belief, with respect to the DMF, Laurus has a regular and established place of business located at the principal place of business of PharmaQ in Parsippany N.J., where Laurus regularly conducts business itself and/or through its agent, PharmaQ.

31. On information and belief, Laurus, directly and/or through its agents, seeks to market, distribute and sell generic pharmaceutical products throughout the United States, including in this judicial district. On information and belief, Laurus manufactures API for generic pharmaceutical products sold throughout the United States, including in this judicial district.

32. On information and belief, Laurus derives substantial revenue from the sale of generic pharmaceutical products throughout the United States, including in this judicial district, directly and/or through its agents.

33. On information and belief, Laurus has invoked this Court's jurisdiction as Counterclaimant in a Hatch-Waxman litigation involving corporate affiliates of Janssen. *See* Answer and Counterclaims (Dkt. 37), *Mitsubishi Tanabe Pharma Corp. et al. v. MSN Laboratories Pvt. Ltd. et al.*, Case No. 3:17-cv-05302-PGS-DEA (D.N.J. Dec. 11, 2017).

34. On information and belief, Laurus has also consented to personal jurisdiction in this district in a Hatch-Waxman litigation. *See* Answer (Dkt. No. 37) at ¶ 41, *Mitsubishi Tanabe Pharma Corp. et al. v. MSN Laboratories Pvt. Ltd. et al.*., Case No. 3:17-cv-05302-PGS-DEA (D.N.J. Dec. 11, 2017) ("Laurus will not contest personal jurisdiction for purposes of this action only.").

35. On information and belief, Laurus has been and is engaging in activities directed toward infringement of the patents-in-suit by, among other things, preparing and

submitting the DMF seeking FDA approval to manufacture API for the ANDA Products and acting in concert with DRL in the preparation and submission of the ANDA seeking FDA approval to market the ANDA Products before expiration of the patents-in-suit throughout the United States, including in New Jersey. On information and belief, Laurus will manufacture the ANDA Products and the API for the ANDA Products.

36. On information and belief, in concert with DRL, Laurus intends to engage in the commercial manufacture, use, or sale of the ANDA Products before expiration of the patents-in-suit throughout the United States, including in New Jersey. The conduct of Laurus, acting itself or through its agent DRL, will therefore cause injury to Janssen in New Jersey.

37. On information and belief, this Court has personal jurisdiction over PharmaQ, *inter alia*, because PharmaQ's principal place of business is located in New Jersey and because PharmaQ is a corporation organized and existing under the laws of New Jersey.

38. On information and belief, this Court has personal jurisdiction over PharmaQ because PharmaQ has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, PharmaQ has had persistent and continuous contacts with this judicial district, including supporting the developing, manufacturing, marketing, and selling of pharmaceutical products that are sold in this judicial district.

39. On information and belief, PharmaQ derives substantial revenue from acting as U.S. regulatory agent with respect to generic pharmaceutical products sold throughout the United States, including in this judicial district.

40. On information and belief, PharmaQ provides material support for U.S. regulatory applications, including the DMF, from its Parsippany, New Jersey offices. On

information and belief, PharmaQ has acted as Laurus's U.S. regulatory agent with respect to the DMF. On information and belief, PharmaQ has acted in concert with DRL and Laurus in seeking approval of the DMF and ANDA.

41. This Court's exercise of personal jurisdiction over Defendants is fair and reasonable. Defendants are not unduly burdened by litigating this suit in this judicial district. New Jersey has an interest in providing a forum to resolve Hatch-Waxman litigation, including this case, which involves the sale of products in New Jersey and parties doing business in New Jersey. This Court's exercise of jurisdiction will serve the interests of the parties and the judicial system in efficient resolution of litigation.

42. In the alternative, as to DRL Ltd. and Laurus, this Court's exercise of personal jurisdiction over DRL Ltd. and Laurus is also proper pursuant to Federal Rule of Civil Procedure 4. On information and belief, DRL Ltd. is a company organized and existing under the laws of India, with a principal place of business in Hyderabad, India. On information and belief, Laurus is a company organized and existing under the laws of India, with a principal place of business in Hyderabad, India.

43. Under Rule 4(k)(2), for a claim arising under federal law, jurisdiction in any federal court is proper where a defendant is (1) not subject to jurisdiction in any state, and (2) exercise of jurisdiction is consistent with the United States Constitution and laws.

44. DRL Ltd. has availed itself of the laws of the United States by, among other things, seeking FDA approval for the ANDA Products and other generic pharmaceutical products. DRL Ltd. also has invoked the jurisdiction of the courts of the United States, including in this judicial district.

45. Laurus has availed itself of the laws of the United States by, among other

things, filing the DMF seeking FDA approval to manufacture API for the ANDA Products and other generic pharmaceutical products and acting in concert with DRL in seeking FDA approval for the ANDA Products. Laurus also has invoked the jurisdiction of the courts of the United States, including in this judicial district.

46. Litigating in the District of New Jersey would not burden DRL Ltd. and Laurus unduly. Among other things, on information and belief, DRL Ltd.'s U.S.-based operations are conducted from the corporate office of DRL USA in Princeton, New Jersey and Laurus's U.S. agent for purposes of its DMF is located in New Jersey. The United States has a substantial interest in adjudicating the dispute and enforcing its patent laws. Janssen has a substantial interest in obtaining convenient and effective relief for violations of its property interests. And the states also have a shared interest in furthering the fundamental substantive policy of the United States with respect to its intellectual property laws.

47. Venue is proper in this district for DRL USA pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, DRL USA is a company organized and existing under the laws of New Jersey and therefore resides in this judicial district.

48. Venue is proper in this district for DRL Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, DRL Ltd. is a company organized and existing under the laws of India and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

49. Venue is proper in this district for Laurus pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Laurus is a company organized and existing under the laws of India and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

50. Venue is proper in this district for PharmaQ pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, PharmaQ is a company organized and existing under the laws of

New Jersey and therefore resides in this judicial district.

51. DRL Ltd. and DRL USA consent to personal jurisdiction and venue in this judicial district for purposes of this action.

BACKGROUND

52. On August 27, 2013, the U.S. Patent and Trademark Office ("PTO") issued the '987 Patent, entitled "Pseudopolymorphic forms of a HIV protease inhibitor." A true and correct copy of the '987 Patent is attached hereto as Exhibit A.

53. Janssen Sciences Ireland UC holds title to the '987 Patent.

54. The '987 Patent expires on February 16, 2024.

55. The FDA has awarded 6 months of pediatric exclusivity for PREZISTA® (darunavir). The period of pediatric exclusivity applicable to the '987 Patent does not expire until August 16, 2024.

56. Janssen Products, L.P. is the holder of approved New Drug Application No. 21-976 for PREZISTA®.

57. Janssen Products, L.P. sells Janssen's PREZISTA® in the United States.

58. PREZISTA® is included in the FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's ANDA to obtain approval of the ANDA applicant's drug product under the provisions of 21 U.S.C. § 355(j).

59. The FDA's "Orange Book" also lists patents associated with approved drugs. The '987 is listed in the "Orange Book" in association with PREZISTA®. The claims of the '987 Patent cover PREZISTA®.

60. On October 24, 2006, the PTO issued the '015 Patent, entitled "Method for the Preparation of Hexahydro-furo-[2,3-b]furan-3-ol." A true and correct copy of the '015 Patent is attached hereto as Exhibit B.

61. Janssen Sciences Ireland UC holds title to the '015 Patent.

62. The '015 Patent expires on June 21, 2023.

63. On September 29, 2009, the PTO issued the '408 Patent, entitled "Method for the Preparation of (3R,3aS,6aR) Hexhydro-furo[2,3-b]furan-3-ol." A true and correct copy of the '408 Patent is attached hereto as Exhibit C.

64. Janssen Sciences Ireland UC holds title to the '408 Patent.

65. The '408 Patent expires on May 6, 2025.

66. The '015 Patent and the '408 Patent claim processes useful for the preparation of (3R,3aS,6aR)hexahydro-furo[2,3-b]furan-3-ol ("bis-THF"), an essential component of darunavir.

67. On information and belief, Defendants have made and will continue to make substantial and meaningful preparations to import into the United States and/or offer to sell, sell, and/or use within the United States products which are made by a processes patented by the '015 and '408 Patents prior to their expiration.

68. On information and belief, Defendants' preparations include, but are not limited to, the development of the ANDA Products, the filing of the ANDA with a Paragraph IV certification, and the filing of the DMF.

69. On information and belief, Defendants intend to use the processes claimed in the '015 and '408 Patents to prepare the bis-THF component of the ANDA Products.

70. On information and belief, that bis-THF is incorporated into and present in

the drug substance (darunavir) in the ANDA Products, intact and without material change from the bis-THF made by use of Janssen's patented processes.

71. On information and belief, the bis-THF resulting from Janssen's patented processes is an essential component of the ANDA Products.

72. Immediately after receiving the Paragraph IV letter, on April 18, 2018, Janssen contacted DRL and asked for information documenting the process that has been and will be used to manufacture bis-THF for the ANDA Products so that Janssen could evaluate infringement of the '015 and '408 Patents. Despite repeated requests, DRL has not provided Janssen with the needed information. In particular, DRL has not provided Janssen with executed batch records, among other documents, showing the process that has been used to manufacture bis-THF for the ANDA Products.

73. Instead, on May 3, DRL provided Janssen with a short, selectively redacted DMF excerpt that is insufficient to determine the process actually used to manufacture bis-THF for the ANDA Product. On May 8, Janssen sent an email to DRL, noting that "DRL's redacted DMF excerpt is obviously insufficient for Janssen to evaluate how bis-THF for DRL's ANDA Product is made," and again requesting the documentation necessary to evaluate infringement of the '015 Patent and the '408 Patent, including executed batch records. Janssen also informed DRL that the route of synthesis described in the DMF excerpt is "commercially infeasible" and requested the full and unredacted DMF as well as executed batch records reflecting how the bis-THF in the ANDA Product was made. Janssen also stressed that "[i]t is in DRL's every interest to provide accurate information as well as needed documents and materials if it contends that it does not infringe Janssen's patents."

74. In its May 8 email to DRL, Janssen also noted that "Laurus's own patent

advocates the use of processes other than [the one described in the Laurus redacted DMF excerpt] for the synthesis of bis-THF. *See* US 9,475,821 at Col. 22." Janssen pointed out that "the only commercial processes that [the Laurus patent] cites are Janssen's patented processes." Indeed, Laurus is the owner of U.S. Patent, No. 9,475,821 (the "Laurus Patent"), which issued in October 2016 and concerns certain processes for the manufacture of darunavir and therefore requires its bis-THF component. The Laurus Patent does not disclose any processes for the production of bis-THF of its own. Rather, the Laurus Patent directs that bis-THF can be "prepared in conventional manner." The only commercial scale processes for the production of bis-THF disclosed in the Laurus Patent are the methods of the '015 and '408 Patents.

75. After several follow-up calls and emails from Janssen, on May 15, DRL wrote an email to Janssen asserting that DRL was "looking into the availability" of the requested information but may object to its production even in litigation. DRL did not deny that 1) the process described in its redacated DMF excerpt is commercially infeasible, 2) that the only commercial processes identified by Laurus for the manufacture of bis-THF are Janssen's patented processes, or 3) that it infringes Janssen's patents for the manufacture of bis-THF.

76. To date, DRL still has not produced the manufacturing information for the bis-THF component of DRL's ANDA Products despite repeated requests. DRL's withholding of needed manufacturing information has impeded Janssen's ability to evaluate infringement of the '015 and '408 Patents.

77. DRL's failure to produce executed batch records or other corroborating manufacturing information for the bis-THF component of its ANDA Products is consistent with the conclusion that the processes invented by Janssen and protected by the '015 and '408 Patents

will be used to manufacture bis-THF for DRL's ANDA Products. On information and belief, DRL has not contested infringement of Janssen's patents and continues to withhold its manufacturing information because the bis-THF component of the ANDA Products is made using the processes claimed in Janssen's '015 and '408 Patents and the importation, use, sale, and/or offer for sale of the ANDA Products would infringe the '015 and '408 Patents.

78. The processes claimed in the '015 and '408 Patents are important for the commercial-scale manufacture of bis-THF. These processes have been infringed by numerous generic companies that have sought to engage in the commercial manufacture, use, offer for sale, and sale of generic versions of PREZISTA® prior to the expiration of the '015 and '408 Patents. *See* Consent Judgment and Order against Hetero Defendants (Dkt. No. 52), *Janssen Prods., L.P. et al. v. Hetero Labs, Ltd. et al.*, Case No. 2:13-cv-01444-WHW-CLW (D.N.J. Oct. 15, 2015) (judgment as to the '015 and '408 Patents); Consent Judgment and Order against Teva Defendants (Dkt. No. 804), *Janssen Prods., L.P. et al. v. Lupin Ltd. et al.*, Case No. 2:10-cv-05954-WHW-CLW (D.N.J. Mar. 26, 2014) (judgment as to the '015 and '408 Patents); Consent Judgment and Order against Cipla Defendants (Dkt. No. 9), *Janssen Prods., L.P. et al. v. Cipla Ltd. et al.*, Case No. 1:15-cv-00307-SLR (D. Del. May 4, 2015) (judgment as to the '015 and '408 Patents); Order Modifying Judgment against Lupin Defendants (Dkt. No. 1075), *Janssen Prods., L.P. et al. v. Lupin Ltd. et al.*, Case No. 2:10-cv-05954-WHW-CLW (D.N.J. Jun. 21, 2016) (judgment as to the '015 Patent); Consent Judgment and Order against Aurobindo Defendants (Dkt. No. 34), *Janssen Prods., L.P. et al. v. Aurobindo Ltd. et al.*, Case No. 2:17-cv-06872-WHW-CLW (D.N.J. Jan. 16, 2018) (judgment as to the '015 and '408 Patents).

79. On information and belief, DRL Ltd., in concert with Laurus, and acting itself or through its subsidiary, alter ego, and agent, DRL USA, submitted the ANDA to the FDA

under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of the ANDA Products. DRL's ANDA has been assigned ANDA No. 21-1578.

80. On information and belief, Laurus, DRL Ltd. and DRL USA collaborated in the research, development, preparation and filing of the ANDA and DMF for the ANDA Products.

81. On information and belief, DRL USA is DRL Ltd.'s authorized U.S. agent for the ANDA.

82. On information and belief, DRL USA will market and/or distribute the ANDA Products if the ANDA is approved by the FDA.

83. On information and belief, Laurus will manufacture the ANDA Products and the API for the ANDA Products if the ANDA is approved by the FDA.

84. On information and belief, PharmaQ has acted as Laurus's U.S. regulatory agent with respect to the DMF for the ANDA.

85. On information and belief, DRL Ltd., Laurus, and PharmaQ participated in, contributed to, aided, abetted and/or induced the submission to the FDA of the ANDA.

86. On information and belief, Defendants have acted in concert in seeking approval of the DMF and ANDA prior to expiration of the patents-in-suit.

87. On or about April 16, 2018, Janssen Sciences Ireland UC and Janssen Products, L.P. received DRL's Paragraph IV Letter stating that DRL has submitted the ANDA to the FDA, seeking approval to manufacture, use, and sell DRL's ANDA Products prior to the expiration of the '987 Patent.

88. DRL's Paragraph IV Letter stated that DRL's ANDA included a

certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '987 Patent are not infringed.

89. DRL does not dispute that the claims of the '987 Patent are valid.

90. Upon receiving DRL's Paragraph IV Letter, Janssen promptly and repeatedly requested production of tablet and API samples of the ANDA Products (in addition to the information concerning the manufacturing processes for the ANDA Products and their essential bis-THF component discussed above), in order to evaluate infringement of Janssen's patents protecting PREZISTA®, including the '987 Patent. DRL agreed that it was in both parties' interest for DRL to provide to Janssen with the information necessary, including samples, for Janssen to evaluate infringement of Janssen's patents. Janssen first requested the production of samples on April 18 and repeated this request on at least April 24, April 26, May 1, May 8, May 11, and May 14. However, despite repeated requests for DRL to provide the needed samples and to ship samples directly to Janssen's expert consultant in Switzerland for analytical testing, DRL did not produce any samples until May 18, 2018, when DRL produced samples of tablets at the offices of Janssen's attorneys in New York. DRL did not produce the tablets until shortly before the expiration of the 45-day period for Janssen to commence this litigation, making any testing within the 45-day period impossible. In addition, DRL failed to produce any samples of API, which are essential for any analysis given the excipients in the tablets. DRL also failed to provide basic analytical testing of its API and ANDA Products despite repeated requests. DRL's failure to produce any samples of API, failure to provide its tablets in a timely manner, and failure to provide basic analytical testing that it has and is trivial to produce impaired Janssen's ability to evaluate infringement of the '987 Patent.

91. DRL's failure to produce the requested samples and documents is consistent with the conclusion that it has and will infringe Janssen's 987 Patent. On information and belief, DRL continues to withhold its analytical testing and the API in its ANDA Products due to infringement of the '987 Patent.

92. On information and belief, the ANDA Products infringe one or more claims of the '987 Patent, either literally or under the doctrine of equivalents.

93. The '987 Patent has been infringed by other generic companies that have sought to engage in the commercial manufacture, use, offer for sale, and sale of generic versions of PREZISTA® prior to the expiration of the '987 Patent. *See* Consent Judgment and Order against Teva Defendants (Dkt. No. 13), *Janssen Prods., L.P. et al. v. Teva Pharms. USA, Inc. et al.*, Case No. 2:13-cv-07576-WHW-CLW (D.N.J. Mar. 26, 2014); Consent Judgment and Order against Cipla Defendants (Dkt. No. 9), *Janssen Prods., L.P. et al. v. Cipla Ltd. et al.*, Case No. 1:15-cv-00307-SLR (D. Del. May 4, 2015); Consent Judgment and Order against Aurobindo Defendants (Dkt. No. 34), *Janssen Prods., L.P. et al. v. Aurobindo Ltd. et al*., Case No. 2:17-cv-06872-WHW-CLW (D.N.J. Jan. 16, 2018).

94. On information and belief, Defendants had actual and constructive notice of the '987, '015 and '408 Patents prior to the filing of the ANDA seeking approval of DRL's ANDA Products, including through judgments in Janssen's favor against other generic manufacturers in this Court.

95. On information and belief, Defendants have made and continue to make substantial preparations in the United States to manufacture, offer to sell, sell and/or import DRL's ANDA Products prior to the expiration of the '987, '015 and '408 Patents.

96. On information and belief, Defendants' actions include, but are not limited to, the development of the ANDA Products, the filing of the ANDA with a Paragraph IV certification, and the filing of the DMF.

97. On information and belief, Defendants continue to seek FDA approval of the ANDA and intend to collaborate in the commercial manufacture, marketing and sale of the ANDA Products (including the commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves the ANDA.

98. Plaintiffs commenced this lawsuit within 45 days of the date they received DRL's notice of ANDA No. 21-1578 containing a Paragraph IV certification.

COUNT I

Infringement of the '987 Patent by DRL under 35 U.S.C. § 271(e)(2)(A)

99. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 98 hereof, as if fully set forth herein.

100. Under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the '987 Patent by submitting ANDA No. 21-1578 with a Paragraph IV certification and seeking FDA approval of ANDA No. 21-1578 to market the ANDA Products prior to the expiration of the '987 Patent.

101. On April 18, Janssen requested production of tablet and API samples for the ANDA Products, among other information, in order to evaluate infringement of Janssen's patents protecting PREZISTA®, including the '987 Patent. Janssen repeated this request on at least April 24, April 26, May 1, May 8, May 11, and May 14. DRL did not produce samples of tablets until shortly before the expiration of the 45-day period for Janssen to commence this litigation, making any testing within the 45-day period impossible, and did not produce any

samples of API. It also failed to provide basic analytical testing of its API and tablets that is trivial to produce. DRL's delays in producing tablet samples and failure to produce any samples of API and other needed documentation impaired Janssen's ability to evaluate infringement of the '987 Patent.

102. On information and belief, including DRL's failure to produce requested samples and information, Defendants' commercial manufacture, importation, use, sale and/or offer for sale of the ANDA Products prior to the expiration of the '987 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '987 Patent either literally or under the doctrine of equivalents.

103. DRL's Paragraph IV Letter does not dispute that the '987 Patent is valid.

104. Defendants had actual and constructive notice of the '987 Patent prior to the filing of ANDA No. 21-1578 seeking approval of the ANDA Products.

105. Janssen has no adequate remedy at law to redress the infringement by Defendants.

106. Janssen will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '987 Patent.

COUNT II

Declaratory Judgment of Infringement of the '015 Patent by Defendants under 35 U.S.C. § 271(g)

107. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 106 hereof, as if fully set forth herein.

108. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Janssen and Defendants regarding infringement of the '015 Patent.

109. On information and belief, Defendants have made and will continue to make substantial and meaningful preparations to import into the United States or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '015 Patent prior to its expiration.

110. Defendants' actions, including, but not limited to, the filing of ANDA No. 21-1578 with a Paragraph IV certification and Defendants' systematic attempts to meet the applicable regulatory requirements for approval of ANDA No. 21-1578 indicate a refusal to change its course of action.

111. On May 3, Janssen received a copy of the ANDA and a short, redacted excerpt from the DMF. On May 8, Janssen informed DRL that the provided documents were insufficient to evaluate infringement of the '015 Patent and repeated its request for the production of executed batch records from the production of bis-THF, among other documentation. On May 15, after several follow-up requests from Janssen, DRL stated that it was "looking into the availability" of the batch records and other documentation but may oppose production of such documents even in litigation. To date, DRL has not produced the requested information. DRL also has not contested infringement of the '015 Patent.

112. On information and belief, including Defendants' failure to produce needed manufacturing information and the fact that Defendants have not contested infringement of the '015 Patent, Defendants' importation, use, sale and/or offer for sale of the ANDA Products prior to the expiration of the '015 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '015 Patent under 35 U.S.C. § 271(g).

113. On information and belief, Defendants had actual and constructive notice of the '015 Patent prior to the filing of ANDA No. 21-1578 seeking approval of the ANDA Products.

114. On information and belief, Defendants' infringement of the '015 Patent is willful.

115. Janssen has no adequate remedy at law to redress infringement by Defendants.

116. Janssen will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '015 Patent.

COUNT III

Declaratory Judgment of Infringement of the '408 Patent by Defendants under 35 U.S.C. § 271(g)

117. Janssen repeats and realleges each and every allegation contained in paragraphs 1 through 116 hereof, as if fully set forth herein.

118. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Janssen and Defendants regarding infringement of the '408 Patent.

119. On information and belief, Defendants have made and will continue to make substantial and meaningful preparations to import into the United States or offer to sell, sell, and/or use within the United States a product which is made by a process patented by the '408 Patent prior to its expiration.

120. Defendants' actions, including, but not limited to, the filing of ANDA No. 21-1578 with a Paragraph IV certification and Defendants' systematic attempts to meet the applicable regulatory requirements for approval of ANDA No. 21-1578, indicate a refusal to

change its course of action.

121. On May 3, Janssen received a copy of the ANDA and a short, redacted excerpt from the DMF. On May 8, Janssen informed DRL that the provided documents were insufficient to evaluate infringement of the '408 Patent and repeated its request for the production of executed batch records from the production of bis-THF, among other documentation. On May 15, after several follow-up requests from Janssen, DRL stated that it was "looking into the availability" of the batch records and other documentation but may oppose production of such documents even in litigation. To date, DRL has not produced the requested information. DRL also has not contested infringement of the '408 Patent.

122. On information and belief, including Defendants' failure to produce needed manufacturing information and the fact that Defendants have not contested infringement of the '408 Patent, Defendants' importation, use, sale and/or offer for sale of DRL's ANDA Products prior to the expiration of the '408 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '408 Patent under 35 U.S.C. § 271(g).

123. On information and belief, Defendants had actual and constructive notice of the '408 Patent prior to the filing of ANDA No. 21-1578 seeking approval of DRL's ANDA Products.

124. On information and belief, Defendants' infringement of the '408 Patent is willful.

125. Janssen has no adequate remedy at law to redress infringement by Defendants.

126. Janssen will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '408 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court grant the following relief:

(a) a judgment that Defendants have infringed the '987 Patent under 35 U.S.C. § 271(e)(2)(A);

(b) a judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of DRL's ANDA No. 21-1578 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) is not earlier than the day after the expiration of the '987 Patent, including any additional exclusivity period applicable to that patent;

(c) a judgment declaring that the making, using, selling, offering to sell, or importing of the generic darunavir tablets described in ANDA No. 21-1578 would constitute infringement of the '987 Patent, or inducing or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

(d) a judgment permanently enjoining Defendants and each of their officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially manufacturing, selling or offering for sale, using, or importing the generic darunavir tablets described in ANDA No. 21-1578, or any colorable variations thereof, until the day after the expiration of the '987 Patent, including any additional exclusivity period applicable to the '987 Patent, and from otherwise infringing one or more claims of the '987 Patent;

(e) a judgment declaring that importing, selling, offering to sell, or using the generic darunavir tablets described in ANDA No. 21-1578 would constitute infringement of the

'015 and '408 Patents, or inducing or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271(g);

(f) a declaration that Defendants' infringement of the '015 and '408 Patents is willful;

(g) a judgment permanently enjoining Defendants and each of their officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially importing, selling, offering for sale, or using the generic darunavir tablets described in in ANDA No. 21-1578, or any darunavir product that includes a bis-THF component made by any colorable variation of the processes used to make the ANDA Products, until after the expiration of the '015 and '408 Patents, and from otherwise infringing one or more claims of the '015 or '408 Patents;

(h) a declaration that this case is exceptional;

(i) an award of Janssen's costs, expenses, reasonable attorneys' fees, and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

(j) such other and further relief as the Court may deem just and proper.

Respectfully submitted,

/s/ John E. Flaherty

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Dated: May 24, 2018

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L. Civ. R. 11.2 that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. However, the matter in controversy involves the validity and infringement of patents previously asserted in this Court against different generic manufacturers in the following actions presided over by the Honorable William H. Walls:

- *Janssen Prods. L.P. et al. v. Lupin Ltd. et al.*, Civil Action No. 10-cv-05954-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Hetero Drugs, Ltd. et al.*, Civil Action No. 13-cv-01444-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Lupin Ltd. et al.*, Civil Action No. 13-cv-03891-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Teva Pharms. USA, Inc. et al.*, Civil Action No. 13-cv-07576-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Lupin Ltd. et al.*, Civil Action No. 14-cv-01370-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Cipla Ltd. et al.*, Civil Action No. 14-cv-05093-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Cipla Ltd. et al.*, Civil Action No. 15-cv-02549-WHW-CLW (D.N.J.);
- *Janssen Prods. L.P. et al. v. Lupin Ltd. et al.*, Civil Action No. 16-cv-01032-WHW (D.N.J.); and
- *Janssen Prods., L.P. et al. v. Aurobindo Ltd. et al.*, Civil Action No. 17-cv-06872-WHW-CLW (D.N.J.).

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